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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,715	09/18/2003	Dimitrios Manoussakis	P-5808	4404
26253	7590	04/10/2008	EXAMINER	
David W. Hight, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880			WRIGHT, PATRICIA KATHRYN	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,715	MANOUSSAKIS ET AL.	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 November 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14, 16-18, 20-60 and 67-86 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 33-60 and 67-86 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14, 16-18 and 20-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed November 27, 2007 in which claim 14 was amended, claims 15, 19 and 61-66 were canceled, and claims 1-13, 33-60 and 67-86 are currently withdrawn. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed. Any objection/rejection not repeated herein has been withdrawn by the Office. New grounds for rejection, necessitated by the amendments are discussed, namely, Applicant's incorporation of claims 15 and 19 into independent claim 14. Note that original claims 15 and 19 both depended from independent claim 14. Therefore, Applicant's incorporation of both these limitations into the claim changes the scope of the invention.

Claims 14, 16-18 and 20-32 are under prosecution.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper.", see par. [0033] of the instant specification. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

3. Claim 20 is objected to under 37 CFR 1.75(c) as being in improper form because it depends on a currently cancelled claim (i.e., claim 19). Accordingly, the claim 20 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14, 16-18, 21-28, and 30-32 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 broadly recites a gel located in a container; the gel having a second region extending upward from a portion of the first region of the gel. It is not clear from the current claims how the claimed gel provides the necessary rheological properties such that a second region extends upward from a portion of the first region, since it is known that not every gel possesses the necessary rheological properties that allow a second region to extend upward from a portion of the first region without being in the process of being centrifuged. Only certain fluids (non- Newtonian; thixotropic) are physically stable enough to remain extending upward from a portion of the first region of a stationary gel. As recognized by Kessler only particular gels do not move or change

shape except when subjected to substantial centrifugal force (see cols. 1 and 2 of US Patent no. 4,350,593 to Kessler).

Claim 14 recites, *inter alia*, the upper boundary of the first region exhibits 360 degree circumferential contact with the inner wall. Claim 25, which depends from claim 14, recites the upper boundary of the first region exhibits 300 to 360 degree circumferential contact with the inner wall. Claim 25 includes a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation. Specifically, claim 25 recites the broad recitation of an upper boundary of the first region exhibiting 300 to 360 degree circumferential contact with the inner wall, and the claim also recites the upper boundary of the first region exhibiting 360 degree circumferential contact with the inner wall which is the narrower statement of the range/limitation. This is considered indefinite, since the resulting claim raises questions or doubts as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1797

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

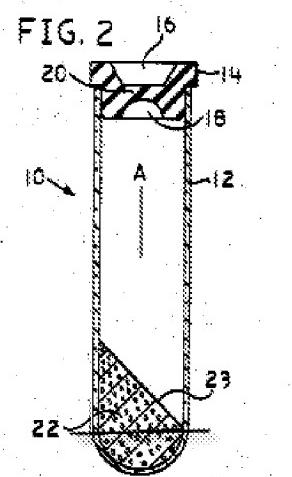
10. Claims 14, 16-18, and 21-32, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kessler (US Patent No. 4,350,593).

Art Unit: 1797

Kessler teaches a container (tube 12) having an upper end, a closed lower end, and a sidewall between the upper and lower ends having inner and outer walls (see col. 3, lines 53- Figs. 2-4). The tube includes a pierceable closure 14 therein (claim 31).

Kessler teaches a thixotropic gel 22 located inside at the lower end of the container contacting a portion of the inner wall (col. 1, line 56- col. 2, line 2; col. 3, line 54- col. 4, line 6; see also Figs. 2-5).

In the interest of clarity, Fig. 2 of Kessler has been modified by the Examiner to include a line or “imaginary upper boundary” that is substantially perpendicular to the longitudinal axis A (see below). The added line is similar to the imaginary upper boundary 44 illustrated in Applicant’s Fig. 3. The line has been added to better illustrate what the Examiner considers the second and first regions of the thixotropic gel 22 (i.e., areas above and below the horizontal line, respectively). Notice the first region (area below the line) exhibits 360 degree circumferential contact with the inner wall, as now recited in claim .



It can be seen in the figure above, the first region of the Kessler gel is located at or adjacent to the lower end of the tube and the second region extends upward from a portion of the first region. The stationary gel of Kessler forms a surface 23 located on a plane which is not perpendicular to the long axis A of the tube (see col. 3, line 61- col. 4, line 6.) Kessler teaches that the surface 23 forms an angle of from about 5 degrees to about 60 degrees with the plane normal the longitudinal axis A of the tube, (see col. 3, lines 64-65). This clearly falls within Applicant's disclosure of the best-fit plane exhibiting 25 degrees or less (claim 22) with respect to a plane substantially perpendicular to the longitudinal axis of the container, and 45 to 90 degree angle with a plane substantially perpendicular to the longitudinal axis of the container.

The thixotropic gel of Kessler is specifically cited in Applicant's instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification. Thus, the Examiner asserts that since the claimed and prior art gels are identical or substantially identical in structure or composition a *prima facie* case of anticipation is established. Further, since the claimed and prior art gels are identical or substantially identical in composition, they must necessarily exhibit the same rheological properties under the same conditions (i.e., in a container). That is, the first region of the gel of Kessler inherently comprises a first region with at least about 80 vol. % of the gel (claim 14), distance between the first and second regions being between 8 to 21 mm (claims 17-18), and the second region exhibits less than 180 degree circumferential contact with the inner wall (claim 27), etc., since See MPEP 2112.02.

However, even if Kessler does not inherently teach the first region comprising at least about 80 vol. % of the gel, it would have been obvious to one having ordinary skill

in the art at the time of the claimed invention to use a gel possessing rheological properties such that at least about 80 vol. % of the gel remains at the bottom of the container (i.e., in the first region), since this would reduce the likelihood of the gel leaking out of the top of container during shipping and storage. Furthermore, the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges resides the optimum combination of percentages. See MPEP 2144.05.

Response to Arguments

11. Applicant's arguments filed November 27, 2007 have been fully considered but they are not persuasive.

In response to the previous rejection of 14-32 and 61-66 under 35 U.S.C. 112, second paragraph, Applicant argues one skilled in the art would understand the metes and bounds of claim 14 when read in light of the specification. Applicant states that claims clearly define a container having a gel therein, wherein the gel has a particular location and geometry; therefore, Applicant concludes one skilled in the art would have no trouble understanding the bounds of claim 14 when read in light of the specification.

The Examiner respectfully disagrees. As discussed above, claim 14 broadly recites a "gel" located in a container and having a second region extending upward from a portion of the first region of the gel. It is well known in the art that not every gel possesses the necessary rheological properties such that a second region extends upward from a portion of the first region without being in the process of being centrifuged. Only certain fluids (non- Newtonian; thixotropic) are physically stable

enough to remain extending upward from a portion of the first region of a stationary gel. These particular gels do not move or change shape except when subjected to substantial centrifugal force (see cols. 1 and 2 of US Patent no. 4,350,593 to Kessler). The Examiner also recognizes that limitations appearing in the specification but not recited in the claim should not be read into the claim. That is, claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily. Thus, the scope of the claim, as currently written, is not clear since only thixotropic gel are able to provide the necessary rheological properties such that a second region extends upward form a portion of the first region.

In response to the previous rejection of 14-32 and 61-65 under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593), Applicant argues Kessler fails to disclose the first region (i.e., area under the imaginary line provided by the Examiner in modified Fig. 2 shown above) comprises at least about 80 vol.% of the gel. Applicant cites as proof that the "majority of the gel" of Kessler allegedly is in the second region (i.e., area above the imaginary line provided by the Examiner in modified Fig. 2 shown above).

The Examiner respectfully disagrees with Applicant's assumptions regarding Kessler. First, Kessler does not indicate the drawings were drawn to scale. It is well known that proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale. See MPEP 2125. When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. It is well established that

patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue. Thus, one cannot reasonably conclude from the drawings that a majority of the gel of Kessler is in the second region (i.e., area above the imaginary line provided by the Examiner in modified Fig. 2 shown above). However, since the thixotropic gel of Kessler is specifically cited in the instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification, the Examiner asserts that the claimed and prior art gels are identical or substantially identical in structure or composition. Therefore, the claimed and prior art gels must exhibit the same rheological properties under the same conditions, that is, the first region of Kessler must necessarily or inherently comprise at least about 80 vol. % of the gel.

The Office hereby requires Applicant prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product. When the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same is similar to that required with respect to product-by-process claims. That is, objective evidence is required to rebut the 35 U.S.C. 102/103 *prima facie* case. See MPEP 2112. It is also noted that during the telephonic interview on November 02, 2007, Applicant agreed to provide objective evidence (i.e., experimental data) that illustrates the gel of Kessler would not inherently result in a first region comprising at least about 80 vol.% of the gel. Applicant has failed to provide any such evidence in the Reply, filed November 27,

2007. Applicant has only argued that Kessler fails to disclose the first region comprises at least about 80 vol.% of the gel based on the modified Fig. 2, which is not to scale.

Therefore, for the reasons delineated above, claims 14, 16-18, and 21-32 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kessler (US Patent No. 4,350,593).

Conclusion

12. No claims allowed.
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-

2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

pkw